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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,417	02/05/2004	Takuya Watanabe	2004_0003	2869
513	7590	04/12/2006	EXAMINER	
WENDEROTH, LIND & PONACK, L.L.P. 2033 K STREET N. W. SUITE 800 WASHINGTON, DC 20006-1021			BUNNER, BRIDGET E	
		ART UNIT	PAPER NUMBER	1647

DATE MAILED: 04/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/771,417	WATANABE ET AL.	
	Examiner	Art Unit	
	Bridget E. Bunner	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 31 January 2006.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-19 is/are pending in the application.
 - 4a) Of the above claim(s) 5-6, 10-16, and 19 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-4,7-9,17 and 18 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 1-19 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 05 February 2004 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. 09/830,428.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 - 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 - 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2/5/04.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
 - 5) Notice of Informal Patent Application (PTO-152)
 - 6) Other: Appendix A, B

DETAILED ACTION***Election/Restrictions***

Applicant's election of Group II, claims 1-4, 7-9, and 17-8, drawn to an isolated polynucleotide which contains a base sequence 95% homologous to SEQ ID NO: 6 in the reply filed on 31 January 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 5-6, 10-16, and 19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 31 January 2006.

Claims 1-4, 7-9, and 17-18 are under consideration in the instant application as they read upon SEQ ID NO: 6.

Information Disclosure Statement

It is noted that two references have been crossed off of the information disclosure statement filed 05 February 2004 because they were cited in duplicate.

Drawings

1. Figures 1-3 and 5-7 are objected to because tables and sequence listings that are included in the specification are, except for applications filed under 35 U.S.C. 371, not permitted to be included in the drawings (see 37 CFR 1.83(a) and 1.58(a); MPEP § 608.02). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being

amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

2. The abstract of the disclosure is objected to because it is more than one paragraph in length and exceeds 150 words. Correction is required. See MPEP § 608.01(b).
3. The disclosure is objected to because of the following informalities:
 - 3a. An updated status of the parent nonprovisional application should be included in the first sentence of the specification. A statement reading "This is a divisional of U.S. Application No. 09/830,428, filed April 26, 2001, Patent No. 6,699,965" should be entered.
 - 3b. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: "POLYNUCLEOTIDE ENCODING THE hOT7T175 G PROTEIN COUPLED RECEPTOR".

Appropriate correction is required.

Claim Objections

4. Claims 1-2, 4, and 8-9 are objected to because of the following informalities:
 - 4a. Claims 1-2, 4, and 8-9 recite a non-elected group.
 - 4b. Claim 4 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 4 recites that the polynucleotide of claim 3 is a DNA containing the base sequence represented by SEQ ID NO: 6. However, claim 3 (which depends from claim 1) recites an isolated polynucleotide which contains a base sequence identical to the represented by SEQ ID NO:6 and wherein the polynucleotide is a DNA.

Appropriate correction is required.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-4, 7-9, and 17-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for (i) an isolated polynucleotide comprising the nucleic acid sequence of SEQ ID NO: 6 and (ii) an isolated polynucleotide comprising the nucleic acid sequence which encodes the polypeptide sequence of SEQ ID NO: 5, *does not* reasonably provide enablement for an isolated polynucleotide which contains a base sequence identical to or at least 95% homologous to that represented by SEQ ID NO: 6. The specification also does not reasonably provide enablement for an isolated polynucleotide which hybridizes to a base

sequence represented by SEQ ID NO: 6. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification of the instant application discloses that “[t]he polynucleotide comprising a part of the base sequence of DNA encoding the receptor protein of the present invention or a part of the base sequence complementary to the DNA is intended to include not only DNA encoding the partial peptide of the present invention as described below but also RNA” (pg 31, lines 16-21). The specification also teaches that “[e]xamples of the DNA that is hybridizable to the base sequence represented by SEQ ID NO: 2 or SEQ ID NO: 6 include DNA having at least about 70% homology, preferably at least about 80% homology, more preferably at least about 90% homology, most preferably at least about 95% homology, to the amino acid sequence represented by SEQ ID NO: 2 or SEQ ID NO: 6” (pg 30, lines 20-26). The Examiner has broadly interpreted the phrase “a base sequence....represented by SEQ ID NO: 6” as reading upon nucleic acid fragments of SEQ ID NO: 6 and nucleic acid variants with any number of deletions, substitutions, or additions. Additionally, claim 2 encompasses an infinite number of polynucleotides that hybridize to the nucleic acid sequence of SEQ ID NO: 6. However, the specification does not teach any variant, fragment, or derivative of the hOT7T175 nucleic acid other than the full-length nucleic acid sequence of SEQ ID NO: 6. The specification also does not teach functional or structural characteristics of the nucleic acid variants, fragments, and derivatives recited in the claims.

The problem of predicting protein and DNA structure from sequence data and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein and

DNA is extremely complex. While it is known that many amino acid substitutions are generally possible in any given protein the positions within the protein's sequence where such amino acid substitutions can be made with a reasonable expectation of success are limited. Certain positions in the sequence are critical to the protein's structure/function relationship, e.g. such as various sites or regions directly involved in binding, activity and in providing the correct three-dimensional spatial orientation of binding and active sites. These or other regions may also be critical determinants of antigenicity. These regions can tolerate only relatively conservative substitutions or no substitutions (see Wells, 1990, Biochemistry 29:8509-8517; Ngo et al., 1994, The Protein Folding Problem and Tertiary Structure Prediction, pp. 492-495). However, Applicant has provided little or no guidance beyond the mere presentation of sequence data to enable one of ordinary skill in the art to determine, without undue experimentation, the positions in the DNA and protein which are tolerant to change (e.g. such as by amino acid substitutions or deletions), and the nature and extent of changes that can be made in these positions. Even if an active or binding site were identified in the specification, they may not be sufficient, as the ordinary artisan would immediately recognize that an active or binding site must assume the proper three-dimensional configuration to be active, which conformation is dependent upon surrounding residues; therefore substitution of non-essential residues can often destroy activity. The art recognizes that function cannot be predicted from structure alone (Bork, 2000, Genome Research 10:398-400; Skolnick et al., 2000, Trends in Biotech. 18(1):34-39, especially p. 36 at Box 2; Doerks et al., 1998, Trends in Genetics 14:248-250; Smith et al., 1997, Nature Biotechnology 15:1222-1223; Brenner, 1999, Trends in Genetics 15:132-133; Bork et al., 1996, Trends in Genetics 12:425-427).

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6. Furthermore, claims 8-9 recite that isolated polynucleotide of SEQ ID NO: 6 is for diagnosis of diseases associated with expression of the polypeptide and for the treatment of diseases associated with expression of the polynucleotide. It is noted that the Examiner has interpreted the phrases "which is for the diagnosis of" and "which is for the treatment of" as intended uses of the polynucleotide. The specification of the instant application teaches that the DNA encoding the receptor protein of the present invention can be used as a prophylactic, therapeutic, or diagnostic agent for diseases associated with the dysfunction of the receptor (pg 69-70, 74). The specification also teaches that the G protein coupled receptor of the instant application may be used for gene therapy by transfer of the receptor gene into the body (pg 4, lines 8-22; pg 31-35; pg 119). However, the specification does not disclose any methods or working examples that indicate the polynucleotide of SEQ ID NO: 6 is a diagnostic or therapeutic for all possible diseases. Undue experimentation would be required of the skilled artisan to determine a nexus between hOT7T175 expression and all possible diseases, other than cancer. Furthermore, the specification does not teach any methods or working examples that indicate a hOT7T175 nucleic acid is introduced and expressed in the cell of an organism for therapeutic purposes. The disclosure in the specification is merely an invitation to the artisan to use the current invention as a starting point for further experimentation. For example, the specification does not teach what type of vector would introduce the hOT7T175 nucleic acid into the cell or in what quantity and duration. Relevant literature teaches that since 1990, about 3500 patients have been treated via gene therapy and although some evidence of gene transfer has been seen, it has generally been inadequate for a meaningful clinical response (Phillips, A., J Pharm Pharmacology 53: 1169-1174, 2001; abstract). Additionally, the major challenge to gene

therapy is to deliver DNA to the target tissues and to transport it to the cell nucleus to enable the required protein to be expressed (Phillips, A.; pg 1170, ¶ 1). Phillips also states that the problem with gene therapy is two-fold: 1) a system must be designed to deliver DNA to a specific target and to prevent degradation within the body, and 2) an expression system must be built into the DNA construct to allow the target cell to express the protein at therapeutic levels for the desired length of time (pg 1170, ¶ 1). Therefore, undue experimentation would be required of the skilled artisan to introduce and express a hOT7T175 nucleic acid into the cell of an organism.

Due to the large quantity of experimentation necessary to generate the infinite number of derivatives recited in the claims and possibly screen same for activity, to diagnose all possible diseases, and to introduce and express a hOT7T175 nucleic acid into a cell of an organism; the lack of direction/guidance presented in the specification regarding which structural features are required in order to provide activity and how to introduce a hOT7T175 nucleic acid in the cell of an organism to be able produce that hOT7T175; the absence of working examples directed to same; the complex nature of the invention; the state of the prior art which establishes the unpredictability of the effects of mutation on protein structure and function and the unpredictability of transferring genes into an organism's cells; and the breadth of the claims which fail to recite any structural or functional limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

7. Claims 1-4, 7-9, and 17-18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

application was filed, had possession of the claimed invention. It is noted that the Examiner has interpreted claim 2 as encompassing an infinite number of polynucleotides that hybridize to the nucleic acid sequence of SEQ ID NO: 6.

The claims are directed to an isolated polynucleotide which contains a base sequence identical or at least 95% homologous to that represented by SEQ ID NO: 6. The claims recite an isolated polynucleotide which hybridizes to a base sequence represented by SEQ ID NO: 6. The claims recite an agent comprising the polynucleotide, a recombinant vector, and a transformant comprising the vector. It is noted that the Examiner has interpreted claim 2 as encompassing an infinite number of polynucleotides that hybridize to the nucleic acid sequence of SEQ ID NO: 6. The Examiner has also broadly interpreted the phrase “a base sequence...represented by SEQ ID NO: 6” as reading upon nucleic acid fragments of SEQ ID NO: 6 and nucleic acid variants with any number of deletions, substitutions, or additions. The claims do not require that the nucleic acid or polypeptide possess any particular biological activity, nor any particular conserved structure, or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of nucleic acids that is defined only by sequence identity.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of a recitation of percent identity. There is not even identification of any particular portion of the structure that must be conserved. Accordingly, in

the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus. Additionally, the description of one polynucleotide species (SEQ ID NO: 6) and one polypeptide species (SEQ ID NO: 5) is not adequate written description of an entire genus of functionally equivalent polynucleotides which incorporate all variants and fragments and with at least 95% sequence identity to a nucleic acid comprising the sequence of SEQ ID NO: 6.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*” (See page 1117). The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed” (See *Vas-Cath* at page 1116).

With the exception of the sequences referred to above, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF’s were found to be unpatentable due to

lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only an isolated nucleic acid comprising the nucleic acid sequence of SEQ ID NO: 6 or an isolated nucleic acid molecule encoding the polypeptide of SEQ ID NO: 5, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1, 3-4, 7-9, and 17-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claims 1, 3-4, 7-9, and 17-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite because it is unclear whether the phrases “which contains” or “containing” is open or closed term language (see claims 1, 4, and 8-9, for example). See MPEP § 2111.03. (This issue could be overcome by amending the claims to recite, for example, “An isolated polynucleotide comprising a nucleic acid sequence of SEQ ID NO: 6.”)

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by Bell et al. (U.S. Patent 5,436,155). It is noted that the Examiner has interpreted claim 2 as encompassing an infinite number of polynucleotides that hybridize to the nucleic acid sequence of SEQ ID NO: 6.

Bell et al. teach an isolated nucleic acid sequence that is 14.6% identical to the nucleic acid sequence of SEQ ID NO: 6 of the instant application (Please see SEQ ID NO: 9 of Bell et al. and the sequence alignment attached to this Office Action as Appendix A). Thus, Bell et al. teach an isolated nucleic acid that hybridizes to the nucleic acid sequence of SEQ ID NO: 6 of the instant application.

11. Claims 1-4, 8-9, and 17-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Borowsky et al. (US20020077469) (priority to 3/10/1999).

Borowsky et al. teach an isolated nucleic acid molecule that is 99.9% identical to the nucleic acid sequence of SEQ ID NO: 6 of the instant application (Please see SEQ ID NO: 1 of Borowsky et al. and the sequence alignment attached to this Office Action as Appendix B). Borowsky et al. also disclose that the SNORF11 receptor of SEQ ID NO : 1 will serve as a tool for the diagnosis and treatment of various pathophysiological conditions (pg 2, [0024]). Borowsky et al. teach a recombinant vector comprising the SNORF11 polynucleotide and an isolated transformant comprising the vector (pg 2, [0025]-[0032]).

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (571) 272-0881. The examiner can normally be reached on 8:30-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BEB
Art Unit 1647
06 April 2006

Bridget E. Bunner
BRIDGET BUNNER
PATENT EXAMINER

Appendix B